

REMARKS

I. PRELIMINARY REMARKS

Claim 9 has been amended. Claims 58 and 59 have been added. No claims have been canceled. Claims 1-9, 28-34 and 37-59 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that the Examiner has indicated that claims 2-8 and 28-34 are directed to patentable subject matter.

II. DOUBLE PATENTING REJECTION

Claim 1 has been rejected under the judicially created doctrine of obviousness-type double patenting over claim 19 of U.S. Patent No. 6,579,288. Applicant respectfully submits that the obviousness-type double patenting rejection has been obviated by the Terminal Disclaimer that was filed in the present application on June 3, 2003 and should be withdrawn. More specifically, the June 3, 2003 Terminal Disclaimer disclaimed the terminal part of any patent granted on the present application that would extend beyond the expiration date of the full statutory period of any U.S. patent granted on U.S. application Serial No. 09/652,099, which is the application from which U.S. Patent No. 6,579,288 was granted.

III. PRIOR ART REJECTIONS

A. The Rejections

Claims 9 and 49-57 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,584,872 to LaFontaine ("the LaFontaine '872 patent") and U.S. Patent No. 5,792,140 to Tu ("the Tu '140

patent"). Claims 37-48 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the LaFontaine '872 patent, the Tu '140 patent and U.S. Patent No. 5,797,903 to Swanson ("the Swanson '903 patent"). The rejections under 35 U.S.C. § 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Cited References

The LaFontaine '872 patent discloses a variety of different RF energy treatment devices. Each of the treatment devices includes a single electrode and a structure, within which the electrode is recessed, for conveying an electrolytic fluid through the electrode to the tissue being treated. Conveying electrolytic fluid to the tissue serves two primary purposes – **(1) establishing an electrical path** from the electrode to the tissue, and **(2) cooling the tissue** so that deeper lesions may be formed. [Column 8, lines 13-32.] Referring to Figure 5, the RF treatment device 78 illustrated therein includes an expandable member 80 with perforations 96. The expandable member 80 is carried on the distal end of a catheter tube 84, which has a single lumen 40 for one directional flow. The proximal end of the catheter tube 84 is connected to a manifold 12 with ports 16A and 16B. [Column 5, lines 33-37.] Port 16B is connected to a source of fluid by a conduit 26. [Column 6, lines 11-13.] An electrode 89 with a distal opening and apertures 92 is also supported on the distal end of the catheter tube 84. Conductive fluid flows through the catheter tube 84 and electrode 89, into expandable member 80, and through the perforations 96 to establish an electrical path between the electrode 89 and tissue as well as to cool the tissue.

The Tu '140 patent discloses a catheter 2 including a tip electrode 12 with a plurality of hollow needles 13 and a band electrode 14 with a plurality of hollow needles 15. Each of the needles defines a passage 20 and an outlet port 21, which direct fluid from the interior of the catheter 2, through the electrodes 12 and 14, and to the tissue surface (as well as to the surface of the electrodes).

The Swanson '903 patent discloses a tissue heating device that includes a catheter tube 12, an inflatable body 22 that permits ionic transfer and prevents fluid perfusion, and an electrode 30 within the inflatable body. During use, the inflatable body is filled with conductive fluid. Energy from the electrode 30 that passes through the conductive fluid also passes through the inflatable body because the inflatable body permits ionic transfer.

C. The Rejection of Claim 9

Independent claim 9 calls for a combination of elements comprising "a shaft," "a plurality of energy transmission devices," "a tissue cooling apparatus ... fluid transmission space is defined therebetween having an inlet and an outlet," "a drainage tube" and "a fluid supply line associated with the inlet and supported ***on the exterior of the shaft at the inlet.***" The cited references fail to teach or suggest such a combination.

For example, the Office Action has taken the position that the LaFontaine catheter tube 84 corresponds to the claimed "shaft" and that the conduit 26 corresponds to the claimed "fluid supply line."¹ Even assuming for the sake of argument that this is a reasonable interpretation of the claim, the conduit 26 is not supported on the catheter tube 84 and, instead, is plugged into the port 16B on the manifold 12, which is in turn attached to the proximal end of the catheter tube. [Note Figure 1 and column 13, lines 58-62.] Additionally, in view of the fact that the conduit 26 does not even appear to reach the proximal end of the catheter tube 84, let alone to the distal end, it certainly is not supported on the exterior of the catheter tube at the inlet to the expandable member 80.

The Tu '140 patent discloses a catheter with an internal fluid supply lumen and, therefore, fails to remedy the aforementioned deficiencies in the LaFontaine '872 patent.

¹ The reference to catheter tube 14 on page 2 of the Office Action appears to be a typographical error given that the Office Action is referring to the embodiment with the expandable member 80 (and catheter tube 84) illustrated in Figure 5.

Accordingly, even when improperly combined in the manner proposed in the Office Action, the LaFontaine '872 and Tu '140 patents fail to teach or suggest the combination defined by independent claim 9. The rejection of claim 9 under 35 U.S.C. § 103 should, therefore, be withdrawn.

D. The Rejection of Claims 37-57

1. The Legal Standards

With respect to the legal standard upon which patentability under 35 U.S.C. § 103 is evaluated, *In re Kotzab*, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000), which is cited in Section 2143.01 of the MPEP, provides a fairly succinct summary of the standard adhered to by the Federal Circuit:

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, ***identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.***

[Citations omitted, emphasis added.] The "motivation, suggestion or teaching" requirement may be satisfied "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002). Here, the outstanding Office Action completely ignores the objective standard for evaluating patentability set forth by the Federal Circuit and instead

engages in an hindsight attempt to piece together the teachings of disparate references to arrive at a holding of obviousness.

2. The Claimed Combinations

Independent claim 37 calls for a combination of elements comprising “a shaft defining a distal end and a proximal end,” “a **plurality of energy transmission devices** supported on the shaft” and “a **tissue cooling apparatus** supported on the shaft including an outer member, configured to permit ionic transfer while substantially preventing fluid perfusion therethrough, **positioned about the plurality of energy transmission devices** such that a continuous fluid transmission space is defined therebetween having an inlet and an outlet.” Claims 38-48 depend from independent claim 37 and the combinations defined thereby include, *inter alia*, the elements recited in independent claim 37.

Independent claim 49 calls for a combination of elements comprising “a shaft defining an exterior, a distal end and a proximal end,” “a **plurality of energy transmission devices** supported on the shaft” and “a **tissue cooling apparatus**, fixedly secured around the exterior of the shaft, including an outer member **positioned about the plurality of energy transmission devices** such that a continuous fluid transmission space having an inlet and an outlet is defined between the tissue cooling apparatus and the exterior of the shaft.” Claims 50-57 depend from independent claim 49 and the combinations defined thereby include, *inter alia*, the elements recited in independent claim 49.

3. Discussion Applicable To Claims 37-57

In contrast to the inventions respectively defined by independent claims 37 and 49, the LaFontaine ‘872 devices clearly lack a combination of elements including “a plurality of energy transmission devices.” Instead, and referring to Figure 5, the LaFontaine ‘872 treatment device 78 includes an expandable member 80 with perforations 96 and a

single electrode 89 within the expandable member. Electrolytic fluid flows through the electrode 89 and out of the expandable member 80 by way of the perforations 96 to the tissue being treated. The Office Action relies on the Tu '140 patent, which discloses a tip electrode 12 and a band electrode 14, to remedy the "a plurality of energy transmission devices" deficiency in the LaFontaine '872 patent. Applicant respectfully submits that it fails to do so.

More specifically, the Office Action states that it would have obvious to include "more than one energy transmitting device" on the LaFontaine device in order to "provide more precise means through selective application for applying energy to targeted tissue." [Office Action at page 4.] There are a variety of errors associated with this statement. Most notably, the statement is not supported by Tu '140 patent. Nothing in the Tu '140 patent even remotely suggests placing more than one electrode **inside an expandable member** that is filled with conductive fluid, and inside the expandable member 80 appears to be only location that the additional electrode(s) would be placed in the purportedly obvious modification of the LaFontaine device.² Nor is there any support for the proposition that, in the context of an expandable member that allows fluid to pass therethrough, "more than one energy transmitting device" inside the expandable member is "more precise" than a single energy transmitting device inside the expandable member.

In view of the foregoing, applicant respectfully submits that the Office Action failed to establish a *prima facie* case obviousness of claims 49-57 and that the rejection of claims 49-57 under 35 U.S.C. § 103 should be withdrawn.

Turning to claims 37-48, applicant respectfully submits that the Swanson '903 patent fails to remedy the deficiencies in the LaFontaine '872 and Tu '140 patents, that Office Action failed to establish a *prima facie* case obviousness, and that the rejection of claims 37-48 under 35 U.S.C. § 103 should be withdrawn.

² As discussed in Section III-D-5 below, applicant respectfully requests that the Examiner specifically indicate where the additional electrode(s) would be located in the purportedly obvious modification of the LaFontaine device.

4. Additional Discussion Concerning Claims 37-48

Applicant respect submits that claims 37-48 are patentable for reasons in addition to those discussed in Section III-D-3 above. For example, the combination defined by independent claim 37 includes, *inter alia*, “a tissue cooling apparatus ... configured to permit ionic transfer while **substantially preventing fluid perfusion** therethrough.” The cited references also fail to teach or suggest this aspect of the claimed combination.

As noted above, electrolytic fluid flows through the electrode 89 in the LaFontaine device and out of the expandable member 80 to the tissue being treated by way of the perforations 96 in order to (1) establish an electrical path from the electrode to the tissue, and (2) **cool the tissue**. The Office Action has taken the position that it would have been obvious, in view of the teachings of the Swanson '903 patent, to modify the LaFontaine expandable member 80 such that it would **prevent fluid perfusion**. [Office Action at page 5.] However, it is precisely this fluid perfusion that allows the LaFontaine expandable member 80 to cool tissue. The purportedly obvious modification would also eliminate the perforations 96, given that there would be no reason to have perforations which allow the fluid perfusion that the purportedly obvious modification was intended to prevent. Thus, not only would the purportedly obvious modification eliminate one of the elements called for in claim 37 (i.e. the “outlet”), the modification would impermissibly prevent the LaFontaine treatment device 78 from performing one of its intended functions, i.e. cooling tissue. To that end, note that the catheter tube 84 has a single lumen 40 for one fluid directional flow. Thus, there is no way for the modified LaFontaine device, which would not include fluid outlets, to cool tissue by ventilating hot fluid and replacing it with cooler fluid during a coagulation procedure.³

Accordingly, for reasons in addition to those discussed above, applicant respectfully submits that the LaFontaine '872, Tu '140 and Swanson '903 patents fail to teach or suggest the combination of elements recited in independent claim 37, whether

viewed alone or in combination, and that the rejection of claims 37-48 under 35 U.S.C. § 103 should be withdrawn.

5. Response to Certain Issues Raised By Office Action

In response to arguments similar to those in Section III-D-3 above concerning the impropriety of proposed “more than one electrode” modification of the LaFontaine device, the outstanding Office Action indicates that “language toward electrodes inside an expandable member is not found in the related claims.” [Office Action at page 6.] Applicant respectfully notes that this particular argument did not concern an element in the claims which is absent from both of the cited references. Rather, the argument concerned the purportedly obvious modification LaFontaine device. Accordingly, applicant respectfully requests that the Examiner indicate in the next Office Action where the additional electrode(s) would be placed in the purportedly obvious modified version of the LaFontaine device (i.e. within the expandable member 80 or at some other specific location) in order to clarify the issues for appeal.

The outstanding Office Action indicates that “judicial notice” has not been taken with respect to the concept of including more than one electrode on the LaFontaine device. [Office Action at page 6.] Applicant respectfully notes that the issue of “judicial notice” was not raised in response to the modification of the LaFontaine device generally, but was instead raised in response to the statement in the previous Office Action that the use of more than one electrode on the LaFontaine device would “provide more precise means through selective application for applying energy to targeted tissue.” [This statement is repeated in the outstanding Office Action.] There is clearly no support in the LaFontaine ‘872 and Tu ‘140 patents for proposition that two (or more) electrodes provide any better power control than one electrode *in a device*, such as the LaFontaine device, *in which conductive fluid is simply flowing past an electrode as it passes through the end of the device on its way to tissue*. As such, the only source of support

³ See MPEP § 2143.01 – proposed modifications cannot “render the prior art unsatisfactory for its intended purpose” and/or “change the principle of operation of

for the "more precise means" statement is the Examiner's opinion concerning what is well known in the art and applicant hereby reiterates the request that the Examiner provide either an affidavit in accordance with MPEP § 2144.03 and 37 C.F.R. § 1.104(d)(2) in support of the statement, or a prior art reference that shows that the statement is accurate.

In response to arguments similar to those in Section III-D-4 above concerning the impropriety of the proposed modification of the LaFontaine device based on the teachings of the Swanson '903 patent, the Office Action states that "[a]pplicant argues that LaFontaine does not disclose prevention of fluid perfusion." [Office Action at page 6.] Applicant respectfully submits that this statement is only partially accurate. As discussed in greater detail above, applicant is not merely arguing that the LaFontaine expandable member 80 allows fluid to flow therethrough (i.e. does not prevent perfusion). Applicant is also arguing that it would not have been obvious to prevent fluid flow through the LaFontaine expandable member 80, as is asserted in the Office Action, because such a modification would prevent the expandable member 80 from performing its tissue cooling function.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

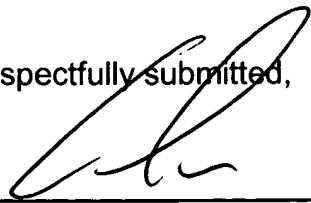
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

a reference."

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

10/20/04
Date

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Respectfully submitted,


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